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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/944,816

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Jay W. Grate

13129-E (50005-50)

1380

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07/26/2006

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EXAMINER

DO, PENSEE T

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/944,816	Applicant(s) GRATE ET AL.	
	Examiner Pensee T. Do	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 February 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) 1-41 and 57-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-59 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Amendment Entry & Claims status***

The amendment filed on February 17, 2006 has been acknowledged and entered.

Claims 1-59 are pending.

Claims 1-41, 57-59 are withdrawn from further consideration.

Claims 42-56 are being examined.

### ***Withdrawn Rejection(s)***

Rejections under 112, 2<sup>nd</sup> paragraph are withdrawn herein.

Rejections under 102 by Chandler and Davidson are withdrawn herein.

### ***Maintained Rejection(s)***

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 42-45, 47, 48, 50, 54-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Blankenstein (US 6,432,630).

Blankenstein teaches a micro flow system comprising a fluid flow path with first and second ends and a capture zone (located on the flow channel where the magnet

Art Unit: 1641

imposes the magnetic field) in between the first and second ends (see fig. 1, col. 12, line 63-col. 13, line 11); a fluid flow controller such as a stepper motor syringe pump that operates in a reversible direction (see col. 17, lines 58-60; col. 18, lines 5-8, lines 45-46); a magnetic field source such as a permanent magnet or an electromagnet (see col. 5, lines 60-65; col. 7, lines 55-58); and an optical detector such as a microscope (see col. 17, lines 20-35). The capture zone is free from fixed magnetizable solid matrix structure. (see fig. 1). Alternative, the system comprises a plurality of capture zones and a plurality of magnetic field sources separated from one another by a zone free of a magnetic field. (see fig. 13, col. 19, line 60-col. 20, line 22). The system also comprises channels for addition of liquids including magnetic particles , which are equivalent to “means for providing in the fluid flow path a first mixture of plurality of solid magnetic particles dispersed in a carrier medium” (see fig. 10, components 57 and 2; fig. 11, inlet port 2; col. 18, lines 31-62). Regarding claim 46, although the magnetic field strength is not taught, it is an inherent property because Blankenstein teaches a magnetic field source as a permanent magnet or an electromagnet, which are the same as that of the present invention. Regarding claim 48, Blankenstein teaches that the channel has a width of 0.1 to .55 mm, depth of 0.04 to 0.2 mm and a length of 20 mm. (see col. 4, lines 38-45). Figure 1 shows that the channel is a shape of a tube with a diameter. Base on the width and depth given by Blankenstein, the diameter of the channel would be 0.2 mm and thus falls within the range of the diameter claimed by the present invention. Regarding claim 47, Blankenstein teaches that the volumetric flow rates range from 0.1 to 200  $\mu\text{L}/\text{min}$ . (see col. 4, lines 49-55). The volume in the capture region in

Art Unit: 1641

Blankenstein is within the volume range as claimed by the present invention. Regarding claim 56, the means for imposing a pulse is defined in the present specification to be a syringe pump, and Blankenstein teaches such pump.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blankenstein (US 6,432,630).

Blankenstein has been discussed above.

However, Blankenstein fails to teach the controller is effective to provide a flow rate in the fluid flow path ranging up to about 2500 mm/s in either direction.

It would have been obvious to one of ordinary skills in the art to use a controller with a flow rate up to about 2500 mm/s in the flow path through routine experimentation depending on how much of the fluid sample there is to be processed. If there is a high concentration of fluid sample needed to be processed, then a higher flow rate is needed.

Claims 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blankenstein (US 6,432,630) in view of Wade et al. (US 5,695,720).

Blankenstein has been discussed above.

However, Blankenstein fails to teach a multiport selective valve including a primary port and a plurality of secondary ports, wherein a first secondary port is fluidly connected to the inlet of the fluid flow path; a holding coil having a proximal end and a distal end; wherein the distal end is fluidly connected to the primary/main port of the selective valve; a three way valve having a first port fluidly connected to the proximal end of the holding coil; a second port fluidly connected to the variable speed reversible pump; and a third port fluidly connected to a source of wash composition.

Wade teaches an apparatus for flow analysis comprising a computer-controlled fluid manipulation and analysis apparatus for chemical, biochemical, and clinical analysis, sample preparation having one or more stream selection hubs with multiple ports through which microliter volumes of multiple fluid streams may be accessed, stacked, mixed and otherwise transferred by two or more pumping systems in a highly repeatable and fully software programmable manner. Figure 1 has a pump 48 connected to a three-way valve, one for a wash solution 44, one for the coil 32. The coil is fluidly connected to the selector valve 20 with a primary valve 16 and a plurality secondary port 14. One of the valves 14 can be vessels containing fluids, such as sample, reagents, wash and other chemical or biochemical fluids or to detectors or to waste container or stream or to other sample processing apparatus. (see col. 8, lines 3-65; figure 1).

It would have been obvious to one of ordinary skills in the art to incorporate the apparatus of Wade into the apparatus of Blankenstein since both devices are used for the purpose of fluid processing or analysis. Both devices need a detector and use

Art Unit: 1641

syringe pumps for controlling fluid flow. Both devices also use coil and three-way valve and are controlled by computer. Thus, one of ordinary skills in the art would have reasonable expectation of success to incorporate into the apparatus of Wade a separation channel with magnets connected to the one of the secondary ports 14 since Wade teaches that port 14 can be attached to vessels containing fluids such as sample, reagents, or other **sample process apparatus**. Such a multiport selective valve taught by Wade can organize the detector, waste chamber of the apparatus of Blankenstein into an orderly functional device.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blankenstein (Us 6,432,630).

Blankenstein has been discussed above.

However, Blankenstein fails to teach a magnetic field strength of from about 0.1 to about 2 kGauss/cm.

Blankenstein discloses the claimed invention except for the specific range listed above. It would have been obvious to one having ordinary skill in the art at the time the invention was made to apply a magnetic field strength from about 0.1-2 Kgauss/cm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

### ***Response to Arguments***

Applicant's arguments filed on February 17, 2006 have been fully considered but they are not persuasive.

Art Unit: 1641

Regarding the rejections by Blankenstein, Applicants argue that since the claims now recite that “the fluid flow controller is effective to impose a pulse in said flow ...” and Blankenstein’s controller is incapable of imposing a pulse to dislodge magnetic particles trapped in the capture zone. In contrast, the fluid flow controller of Blankenstein is configured to operate at variable speeds, it is not configured to impose a pulse, as the system of Blankenstein does not trap particles in a capture zone.

The specification of the present invention discloses the fluid flow controller to be a reversible syringe pump with stepper-motor. (see page 17). Blankenstein teaches a reversible syringe pump with stepper-motor (see col. 17, lines 58-60); col. 18, lines 5-8; lines 45-46). Thus, it would be able to perform the same function as that of the present invention, imposing a pulse to dislodge the magnetic particles.

### ***Remarks***

Claims 47 and 48 were intended to be included in the 102 rejection by Blankenstein in the previous office action. (see explanation of claims 48 and 47 (second occurrence of claim 48) in the previous office action).

Claims 52-53 were amended to change their dependency. Thus, they are now rejected under 103 along with claim 51.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.




Art Unit: 1641

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do  
Patent Examiner  
July 13, 2006

  
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